

33. (amended) A solution hybridization kit for the detection of a target nucleic acid sequence for diagnosing genetic defects, microbial or viral infections in a biological sample with an accuracy of at least 89% comprising:

- B1
- a) a sample transport medium for stabilization of the biological sample;
  - b) an unmodified probe complementary to the target nucleic acid sequence for formation of a double-stranded RNA/DNA hybrid;
  - c) a solid phase to which an anti-hybrid antibody or a functional anti-hybrid antibody fragment has been immobilized, wherein the antibody or antibody fragment specifically binds to a component of the double-stranded RNA/DNA hybrid; and
  - d) means for detecting the hybrid formed by hybridization of the probe and the target nucleic acid sequence.

Please add new claims as follows:

34. (new) A non-radioactive hybridization assay for the detection of a target nucleic acid sequence in a biological sample comprising the steps of:

- B2
- a) hybridizing a nucleic acid sequence in a hydrolyzed sample of cells to a complementary nucleic acid probe to form a double-stranded RNA:DNA hybrid;
  - b) capturing the hybrid onto a solid phase to which an anti-hybrid antibody or functional anti-hybrid antibody fragment has been immobilized, wherein the antibody or antibody fragment specifically binds to a component of the double-stranded RNA:DNA hybrid forming a bound hybrid;
  - c) eliminating any non-hybridized probe; and

d) binding an antibody reactive with a RNA:DNA hybrid to the bound hybrid forming an antibody bound hybrid, thereby detecting the target nucleic acid sequence.

35. (new) The assay according to claim 34, wherein the antibody reactive with a RNA:DNA hybrid is unlabeled, further comprising, binding a labeled antibody reactive with an antibody to the antibody bound hybrid.

36. (new) The assay according to claim 34, wherein the antibody reactive with a RNA:DNA hybrid is labeled.

37. (new) The assay of claim 34, wherein the non-hybridized probe is eliminated by digestion with an enzyme.

38. (new) The assay of claim 34, wherein the concentration of probe is between 1 and 500 ng/ml.

39. (new) The assay of claim 34, wherein the concentration of probe is between 20 and 200 ng/ml.

40. (new) The assay of claim 34, wherein the concentration of probe is approximately 75 ng/ml.

41. (new) A non-radioactive hybridization assay for the detection of a target viral nucleic acid sequence in a biological sample suspected of containing the virus, comprising the steps of:

a) hybridizing the target viral nucleic acid to a complementary nucleic acid probe to form a double-stranded RNA:DNA hybrid;

- b) capturing the hybrid onto a solid phase to which an anti-hybrid antibody or functional anti-hybrid antibody fragment has been immobilized, wherein the antibody or antibody fragment specifically binds to a component of the double-stranded RNA:DNA hybrid forming a bound hybrid;
- c) eliminating any non-hybridized probe; and
- d) binding an antibody reactive with a RNA:DNA hybrid to the bound hybrid forming an antibody bound hybrid, thereby detecting the viral nucleic acid sequence.

42. (new) The assay according claim 41, wherein the target viral nucleic acid sequence is from human papilloma virus (HPV).

43. (new) The assay according to claim 42, wherein the probe comprises HPV 6 and HPV 11.

44. (new) The assay according to claim 42, wherein the probe comprises HPV 16, HPV 18, HPV 31, HPV 33 and HPV 35.

45. (new) The assay according to claim 42, wherein the probe contains one or more HPV types selected from the group consisting of HPV types 6, 11, 33, 42, 43, 44, 16, 18, 31 and 35.

46. (new) The assay of claim 41, wherein the target viral nucleic acid sequence is from hepatitis B virus (HBV).

47. A solution hybridization kit for the detection of a target virus for diagnosing a viral infection in a biological sample with an accuracy of at least 89% comprising:

- a) a sample transport medium for stabilization of the biological sample suspected of containing the virus;
- b) a probe complementary to a target viral nucleic acid sequence for formation of a double-stranded RNA/DNA hybrid;
- c) a solid phase to which an anti-hybrid antibody or a functional anti-hybrid antibody fragment has been immobilized, wherein the antibody or antibody fragment specifically binds to a component of the double-stranded RNA/DNA hybrid; and
- d) means for detecting the hybrid formed by hybridization of the probe and the target viral nucleic acid sequence.

48. (new) A non-radioactive hybridization assay for the detection of a target *Chlamydial* nucleic acid sequence in a biological sample suspected of containing the *Chlamydia*, comprising the steps of:

- a) hybridizing the target viral nucleic acid to a complementary nucleic acid probe to form a double-stranded RNA:DNA hybrid;
- b) capturing the hybrid onto a solid phase to which an anti-hybrid antibody or functional anti-hybrid antibody fragment has been immobilized, wherein the antibody or antibody fragment specifically binds to a component of the double-stranded RNA:DNA hybrid forming a bound hybrid;
- c) eliminating any non-hybridized probe; and
- d) binding an antibody reactive with a RNA:DNA hybrid to the bound hybrid forming an antibody bound hybrid, thereby detecting the *Chlamydia* nucleic acid sequence.

49. A solution hybridization kit for the detection of a *Chlamydial* infection in a biological sample with an accuracy of at least 89% comprising:

- a) a sample transport medium for stabilization of the biological sample suspected of containing the *Chlamydial* infection;
- b) a probe complementary to a target *Chlamydia* nucleic acid sequence for formation of a double-stranded RNA/DNA hybrid;
- c) a solid phase to which an anti-hybrid antibody or a functional anti-hybrid antibody fragment has been immobilized, wherein the antibody or antibody fragment specifically binds to a component of the double-stranded RNA/DNA hybrid; and
- d) means for detecting the hybrid formed by hybridization of the probe and the target *Chlamydia* nucleic acid sequence.

REMARKS

Applicants respectfully request favorable reconsideration in view of the herewith presented amendment and remarks.

Claims 33-49 are pending in the instant application. The amended claim and claim 34-40 are supported throughout the specification and in particular in paragraphs 50, 52, 56 and 59-60 and in the Examples. Claims 41-47 are supported throughout the specification and in particular in paragraph 38 and in Examples 1-5. Claim 48 is supported throughout the specification and in particular in Example 6.

Claims 28-32 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite for the recitation of “antibody fragment” and “functional anti-hybrid fragment”. Applicants believe this rejection is not an issue in the new claims and therefore the issue is moot.